

Attorney Docket No.: **BIS-043/CIP (BI-0004US.P1)**
Inventor: **Simons and Gao**
Serial No.: **09/426,011**
Filing Date: **October 25, 1999**
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REMARKS

Claims 11 and 15-16 are pending in the instant application. Claims 11 and 15-16 have been rejected. Claims 11 and 15-16 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claims 11 and 15-16 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is suggested that while the specification teaches two species of the claimed genus of PR-39 derived oligopeptides, *i.e.*, SEQ ID NO:4 and SEQ ID NO:5, the claim encompasses numerous species that are not further described. It is suggested that claim 11 defines the peptide by function, with the only structure being that the peptide is not substantially greater than 11 amino acids in length, has an N-terminal amino acid residue sequence which begins with Arg-Arg-Arg, and the peptide is devoid of Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro-Pro-X-X-Pro, wherein X is any amino acid. The Examiner suggests that while the function of the envisioned peptide is defined, the structure remains undefined. Applicants respectfully disagree with this rejection.

At the time of filing of the present application, the amino acid sequence of PR-39 was well-known in the art. Applicants have appreciated that the N-terminal amino acid sequence of a PR-39 peptide, *i.e.*, lacking the "Pro-Pro-X-X-Pro-Pro-X-X-Pro" or "Pro-Pro-X-X-X-Pro-Pro-X-X-Pro" intermediate sequence, is sufficient

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to cause a selective inhibition of proteasome-mediated degradation of peptides in-situ. In this regard, a peptide containing at least the first eight N-terminal amino acid residues of PR-39, e.g., Arg-Arg-Arg-Pro-Arg-Pro-Pro-Tyr, is disclosed for selective inhibition of proteasome-mediated degradation. Accordingly, in an earnest effort to more clearly set forth the structure of the instant family of peptides, Applicants have amended claim 11 to indicate that the claimed family of PR-39 derived oligopeptides is 8 to 11 amino acid residues in length and contains the N-terminal amino acid sequence Arg-Arg-Arg-Pro-Arg-Pro-Pro-Tyr (SEQ ID NO:5) as supported by sequence of the PR-8 and PR-11 peptides disclosed at page 26. Claims 15 and 16 have also been amended to specifically read on the PR-8 and PR-11 peptides. In light of these amendments, Applicants believe that a clear and concise description of the structure of the claimed family of PR-39 derived oligopeptides has been provided and the written description requirement has been met. It is therefore respectfully requested that this rejection under 35 U.S.C. 112 be reconsidered and withdrawn.

II. Rejection of Claims Under 35 U.S.C. §103

Claims 11, 15 and 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ross (U.S. Patent No. 6,133,233) for the reasons of record. Specifically, it is suggested that the 14 amino acid peptide of Ross, which includes SEQ ID NO:4 and SEQ ID NO:5 of the instant invention, is not substantially greater than 11 amino acid residues and has an N-terminal amino acid sequence

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of Arg-Arg-Arg. Applicants respectfully traverse this rejection in light of the claims as presently amended.

As indicated above, Applicants have clarified that the claimed family of PR-39 derived oligopeptides is 8 to 11 amino acids in length and contains the N-terminal amino acid sequence of Arg-Arg-Arg-Pro-Arg-Pro-Pro-Tyr. As there is no appreciation by Ross that a PR-39 derived peptide of 8 to 11 amino acids in length is sufficient to cause a selective inhibition of proteasome-mediated degradation of peptides in-situ, this reference cannot be held to make the present invention obvious as it fails to teach or suggest each and every element of the claimed invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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